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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,574	04/25/2005	Hans-Peter Buchstaller	978725.2	4279

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EXAMINER	
MORRIS, PATRICIA L	
ART UNIT	PAPER NUMBER
1625	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,574	BUCHSTALLER ET AL.	
	Examiner	Art Unit	
	Patricia L. Morris	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *6-9 and 11-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/8/06;5/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 and 10 are under consideration in this application.

Claims 6-9 and 11-32 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

Applicant's election with traverse of Group I and example 439 in the reply filed on April 30, 2008 is acknowledged. The traversal is on the ground that there is no burden at all on the examiner to search all the inventions and the examiner is required to search all the inventions. This is not found persuasive for the reasons clearly set forth in the previous Office action. The instant compounds A-D-B do not even belong to a recognized class of compounds. The substituents on the variable core vary extensively and when taken as a whole result in different inventions. The examiner is not required to search additional compounds because the instant compounds fail to make any contribution over the prior art. Applicants are invited to note the numerous anticipatory references cited in the international search report. The international search report recites that so many documents were retrieved that it is impossible to determine which parts of the claim(s) may be said to define subject-matter for which protection might legitimately be sought. Further, the reports states that a meaningful search over the whole breadth of the claims is impossible. Moreover, applicants have failed to advance any cogent reasons as to why the inventions do not lack unity of invention. The request for rejoining Group III with the elected compound cannot be made because it is evidenced that it is well recognized in the art the raf-kinase is a class of enzymes involved in many regulatory mechanisms with other enzymes and physiological systems. Claim 27 is drawn to the treatment and prevention of any and all

unknown disorders. There is no evidence of record that the instant compounds are able to treat and prevent all disorders associated with a raf-kinase. A claim to all raf-kinase mediated disorders is considered a reach through to the continuous development of the field and do not meet the requirements of 35 U.S.C. 112.

It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

The restriction requirement is deemed sound and proper and will be maintained.

The application has been examined to the extent readable on the elected compounds wherein A is (optionally substituted by non-heterocyclic groups) aryl, D is $NHCYNHCH_2$, Y is O or S and B is phenyl substituted by O- (optionally substituted by non-heterocyclic groups) pyridine as set forth in claim 1, exclusively. All additional heterocycles pertain to nonelected subject matter.

Claim Rejections - 35 USC э 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is a lack of description as to how the derivatives and solvates are produced and what solvates and derivatives are produced in the specification. Vippagunata et al. (Advanced Drug Delivery Reviews 48 (2001) 3-26) recites on page 18 that predicting the formation of solvates of a compound and the number of molecules of solvent or water incorporated into the crystal lattice of a compound is complex and difficult. Guillory (in Brittain et al., NY:Marcel Dekker, 1999, pages 183-226, teach that solvates are formed by recrystallization of drug substances. However, not all compounds will form solvates.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparing the instant compound and its salts, does not reasonably provide enablement for preparing any and all unknown solvates or derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification fails to prepare any solvates and derivatives or identify the solvates and derivatives obtained.

The expressionsubstituted is employed with considerable abandon in the claim 1 with no indication given as to what the groups really are.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouche, 169 USPQ 429 CCPA 1971, MPEP 716.02(b).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention

The nature of the invention is the preparation of a compound, its salts, derivatives and solvates.

State of the Prior Art

Predicting the formation of solvates and derivatives of a compound and the number of molecules of solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates and hence generalizations cannot be made for a series of compounds. Note section 3.4 of Vippaguanta et al.

Substituents can have very different properties. Substituents tend to convert from less stable to more stable forms. No method exists to predict what substituent will work with any

significant certainty. Substituents can convert from one form to another during the manufacturing process of a pharmaceutical drug and will change the pharmacological affects of the drug. This is why it is important to monitor the compounds during manufacture of the drug to see if it persists during manufacture.

The amount of direction or guidance and the presence or absence of working examples

The working examples in the specification fail to show how any solvates and derivatives are produced. Further, Guillory on page 199 recites that compounds originally crystallized as solvates can lose the solvent induced by heat or vacuum vaporization.

The specification fails to describe any substituent. Substituents often change into other forms during drug manufacture. Based on the unpredictability in the art, applicants are not entitled to any and all unknown subsituents.

The breadth of the claims

The breadth of the claims is drawn to the preparation of the compound, its salts, derivatives and all solvate forms.

The quantity of experimentation needed

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the process of preparing all unknown solvates.

In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by

applicants. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Genentech Inc v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and [p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms solvate, derivative and subsituted in claims 1-5 are indefinite to their meaning.

The plural 's' on "derivatives, salts and solvates" makes claims 1-5 read on mixtures rather than specific compounds.

Claim 10 is an improper composition claim because it fails to recite the present of an inert carrier.

The claims measure the invention. United Carbon Co. V. Binney & Smith Co., 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 USPQ 11, at 15.

Allowable Subject Matter

Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and if rewritten directed solely to the elected compounds indicated as being examinable, supra.

Claims 2-5 and 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims and if rewritten directed solely to the elected compounds.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia L. Morris/
Primary Examiner, Art Unit 162510

plm
July 14, 2008